

REMARKS

Claims 37-39 are canceled without prejudice due to restrictions imposed by the Examiner and were required to be withdrawn from consideration. Claim 14 and 31 have been amended to specify that the tie layer acts as a barrier to adhesives used to adhere the backing construction to the drug delivery device so that the embossable integrity of the outer layer is maintained. Support for this amendment of claims 14 and 31 can be found, for example, in the specification on paragraphs 0006 and 0032 and in the drawings. Claim 14 has also been amended to specify that the base layer is impermeable to the secondary drug, which is contained in the tie layer, such that the secondary drug cannot permeate to the skin when the drug delivery device is in use. Support for the amendment of claim 14 can be found, for example, in the specification on paragraph 0043 and the drawings. Claims 15, 28 and 31 have also been amended to specify that the first and second layer of the multilaminate tie layer differ in composition, and that the second and third layer of the multilaminate tie layer differ in composition, too. Support for the amendment of claims 15, 28 and 31 can be found, for example, in the specification on paragraph 0029 and the drawings. Claims 16, 21-23, 27 and 32 have been amended to correct a typographical error. New claim 40 is added to claim a multilaminate backing construction that contains a tie layer comprising a sufficiently low melting point material that permits the tie layer to be laminated to the outer layer at a temperature at which the secondary drug is not degraded. Support for the new claim can be found, for example, in the specification on paragraphs 0032 and 0034 and in the drawings. No new matter is added in the amendment or the new claims. Thus, claims 14-16, 18-23, 25-32 and 40 are pending.

35USC §112 rejection

Claims 14-16, 18-23, 25-32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regards as the invention. Claims 14 and 31 have been amended to clearly point out and distinctly claim the subject matter of the invention. In particular, the term “adhesive” has been clarified.

Double Patenting

The Examiner rejected claims 14-16, 18-23, 25-32 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420,428 in view of Steinborn et al. (US6080421) and FR 2249148 (Derwent abstract). Insofar as the rejection is maintained on the amended claims, Applicant respectfully traverses the rejection.

Foremost, the approach used by Steinborn et al. to emboss the backing layer of a transdermal delivery device is totally different to the approach presented by the Applicant. Steinborn describes a two-layer backing containing an external low-melting point thermoplastic layer **4** and a high-melting point thermoplastic layer **5** facing the skin and protecting an active agent containing matrix layer **2** from damage when the low-melting point thermoplastic layer **4** is melted for embossment.

This is different from the labeling backing construction of the present invention. Most importantly, the multilaminate backing construction of the present invention is embossed by application of pressure without melting the outer layer and without increasing the temperature as described in paragraph 0050 of the present application. In particular, by crushing the microporous material of the outer layer during embossment a very striking visual graphic is achieved. Necessary for maintaining embossability of the outer layer is that the tie layer prevents any intrusion of pressure sensitive adhesives into the outer layer, since adhesives would not only render the outer layer transparent, but also dissolve the embossed image.

Nowhere does Steinborn et al. mention that the matrix layer **2** or the high-melting point barrier **5** act as a barrier to adhesives to shield the outer backing layer **4** from intrusion thereof, nor does the composition of Steinborn's backing layer inherently contain such a protective barrier. Rather the opposite, Steinborn's matrix layer contains adhesives, and the surface of the outer layer can be equipped with a skin-like soft touch (col. 1, lines 47-48). The softness of the outer layer material would make it impossible to maintain the integrity of any pressure-embossed image on the outer layer.

Again, the embossing techniques presented in this application – crushing breathable microporous material – in contrast to Steinborn et al.'s technique – deforming a low-melting thermoplastic material into an embossed shape (col. 1, lines 63-65) – are entirely different techniques for embossing a backing layer as anyone skilled in the art would attest to. Each technique requires a very different kind of embossable material.

The Examiner stated that “Steinborn et al. disclose that embossing and printing are known methods to label transdermal therapeutic systems” and “it would have been obvious to label the invention of copending Appl. ‘428 with the embossing method of Steinborn”.

However, since the embossing method used for this invention and the method of Steinborn are totally different in addition to that none of the cited references talks about a protective barrier to adhesives for maintaining embossability, the copending application No. 10/420,428 in view of Steinborn's invention combined with FR 2249148 (Derwent abstract) cannot possibly anticipate the present invention.

Furthermore, the Examiner pointed out that copending Appl. ‘428 combined with FR ‘148 puts the adhesive layer between the reservoir and embossable outer layer. But having the adhesive layer next to the embossable outer layer is exactly what the present invention intends to prevent, since it would degrade the embossability of the outer layer.

It is noted that Steinborn's reference to embossing as a known procedure to label transdermal therapeutic systems (col. 2, lines 7-8) specifically refers to the embossing technique cited in reference DE-Gbm 94 09 784. According to Steinborn, ordinary techniques as cited in DE-Gbm 94 09 784 and accessible to those skilled in the art expose the transdermal system to "an undue and high pressure noxious for the pharmaceutical form of application" (col. 2, lines 29-31) and that obviously "embossing is not done in practice" (col. 2, line 44). These ordinary embossing techniques are therefore insufficient for labeling transdermal delivery system creating exactly the need that the present invention successfully addresses.

Further, in copending Application No. 10/420,428, there is no mention of embossing, so the specification does not support claims about embossment, whereas in the pending claims of the present application, the backing is embossed.

Withdrawal of the objection is requested.

Nevertheless, Applicant reserves the right to submit a terminal disclaimer later if Applicant thinks it may speed the issuance of a patent.

35USC §103(a) rejection

Claims 14, 15, 18-23, 25, 26, 28, and 30 were rejected under 35 U.S.C 103(a) as being unpatentable over Kydonieus et al. (US4758434) in view of Steinborn et al. (US6080421) and evidenced by Gale et al. (US4904475). Insofar as the rejection is maintained on the amended claims, Applicant respectfully traverses the rejection.

Regarding claims 14, 19, and 30, the Examiner asserted that the recited structural relationship between the layers is not given any patentable weight as outer layer/tie layer/base layer. Applicant submits that anyone skilled in the art clearly understands especially in light of the amended claims that the multilaminate backing construction of the present invention is composed of different layers of materials, and further understands the structural and functional relationship of the different layers. The outer layer is a breathable material; the tie layer has a drug and ties the base layer to the outer layer such that an adhesive does not enter the breathable outer layer to maintain embossability of the outer layer. Moreover, the tie layer can itself be a multilaminate layer containing layers of different materials. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d, 180 USPQ 580 (CCPA 1974). Every element has to be considered.

Furthermore, the Examiner asserted that Kydonieus' backing layer, reservoir layer and diffusion membrane layer structurally correspond to the outer layer, tie layer and base layer of the claimed invention. Since the diffusion membrane layer in Kydonieus is permeable to the drug and has the explicit purpose of controlling the diffusion of the drug in the reservoir layer to the skin, Kydonieus diffusion layer cannot possibly anticipate the base layer of the present invention, since the base layer in contrast is impermeable to the secondary drug.

In addition, Steinborn et al. does not anticipate the embossment of the present invention as argued in the above "Double patenting" section. Again, the Examiner asserted that it would have been obvious to emboss the outer backing layer of Kydonieus device because embossing is taught by Steinborn. However, Steinborn only talks about deforming by heat to change the shape in embossing, while Steinborn is entirely silent about crushing of breathable material. Further, there is absolutely no indication that Steinborn teaches a tie layer that does not result in adhesive entering the breathable material in embossment. A limitation cannot be rendered obvious by the complete absence of that limitation in the prior art reference.

Thus, even if one assumes that a person skilled in the art were to try to combine Kydonieus and Steinborn, such a combination will not result in a multilaminate backing construction claimed in the present invention. Further, a combination of Kydonieus and Steinborn will only result in a drug delivery system to be used directly on skin, not result in a backing that is to be placed in a more complex drug delivery system, wherein an adhesive adheres the backing construction to the drug delivery system. Kydonieus system combined with Steinborn's teachings is entirely different from the present invention, which is a multilaminate backing construction for labeling and reducing potential abuse of a drug delivery device.

Hence, claims 15, 18, 20-23, 25, 26, and 28 cannot be anticipated or rendered obvious by combination of Kydonieus with Steinborn, since these claims merely pose limitations on claim 14, which by the above argument itself cannot be anticipated or rendered obvious by combining Kydonieus with Steinborn.

Furthermore, regarding claim 15, the Examiner asserted that in the absence of compositions for the component layers in the tie layer, the component layers are indistinguishable and therefore the Kydonieus' single tie layer reads on the instantly claimed component layers. However, as pointed out above, one skilled in the art will know that a multilaminate must have more than one layer for that is what "multilaminate" means. Any reasonable person knows that "one dancer" cannot mean "a pair of dancers." Similarly, a single tie layer cannot be a multilaminate layer. Additionally, claim 15 specifies that the tie layer contains at least two layers of different materials.

Regarding claims 18, 23, 25, and 28, the Examiner took Official notice that polypropylene microporous membrane is a common backing material for a transdermal delivery system as admitted prior art. However, Applicant traverses because a microporous breathable layer is not used in the prior art as an embossable layer of a multilaminate backing. Kydonieus only mentions that the backing layer may optionally also be a semi-permeable membrane without any further specification to what function the semi-permeable membrane serves in the transdermal device. A semi-permeable membrane does not inherently have features, which makes it suitable for pressure-based embossing. In addition, Kydonieus is absolutely silent about embossing; hence one cannot draw the conclusion that Kydonieus intended the membrane to be embossed. In the state of the art of transdermal delivery devices semi-permeable membranes are used for controlling, for example, the hydration of the drug matrix, allowing free exchange of water moisture with the exterior environment, yet preventing leakage of the drug into the environment.

More importantly, Steinborn does not mention a microporous membrane at all. Far from it, Steinborn exclusively talks about a low-melting point thermoplastic layer on top of a high-melting point thermoplastic layer, with the low-melting point layer being embossed by melting it. Consequently, it is by no means clear to someone skilled in the art as how to combine the teaching of Kydonieus with the teachings of Steinborn to obtain the embossable multilaminate backing construction of this present invention. Since the Examiner in that paragraph argues the anticipation of the microporous breathable layer, the Applicant ask the Examiner to explain in more detail as to how combining the teachings of both references with respect to melting to emboss and the lack of microporous membrane would result in a microporous breathable outer layer that is embossed by applying pressure without melting thereof. Applicant submits Steinborn and Kydonieus cannot be combined to yield the present invention.

The Examiner rejected claims 20 and 26, asserting that Kydonieus' agent encompasses the claimed secondary drug, implying that the antagonist reads on Kydonieus' drug in the drug reservoir. However, Kydonieus' drug reservoir is a reservoir for delivery of a drug to the skin. On the contrary, the antagonist in the present invention is in the backing's tie layer and is not to be delivered to the patient, but rather reduces the potential of abuse for the drug delivery device. Clearly, the drug in the reservoir layer of the present invention and the drug in the Kydonieus reservoir serve diametrically opposed purposes. The antagonist of the present invention is only released when our drug device is subject to abuse, while the drug in the Kydonieus reservoir is intended by Kydonieus to be delivered from the drug reservoir to the skin. Moreover, the antagonist as used in the present invention is an antagonist to the drug of the delivery device. Thus, the Kydonieus drug reservoir should not render obvious the drug utilized in the secondary drug reservoir of the present invention.

The Examiner rejected claims 21 and 22 based on Kydonieus disclosing PVC particles in the plastisol. However, as Applicant points out that Kydonieus discloses a transdermal delivery device and not a backing thereof, and the plastisol is to be attached to a patient when the device is in use, which is entirely different from the present backing invention.

The Examiner rejected claims 16, 31, and 32 as being unpatentable over Kydonieus et al. in view of Steinborn et al. and FR 2249148.

Again, the Examiner relies on the teachings of Kydonieus and Steinborn, and again the Applicant respectfully traverses this rejection as the combination of Kydonieus and Steinborn does not read on this present invention as argued above.

Because FR '148 only discloses an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides and is absolutely silent on embossing the tape, if one would combine FR 2249148 with Kydonieus et al. in view of Steinborn et al., the combination still would not read on the present invention. Furthermore, FR '148 is silent as to how an adhesive tape has to be modified to be operable in the backing of a medical device. It not only has to be toxicologically acceptable, but as Steinborn points out an adhesive intermediate layer usually leads to a bubble containing unattractive appearance (col. 2, line 36-37). On the contrary, the present invention teaches away from placing an adhesive tape of FR '148 as the tie layer next to

the outer layer; the tie layer in the present invention contains a protective barrier for adhesives such as to prevent adhesives from intruding the outer layer, since embossing a laminate with a microporous breathable layer next to an adhesive film causes problems, as clearly described in the present invention.

Further, Steinborn et al. directly contradict the Examiner's statement that "a workable legible embossment without adhesive entering the breathable material deemed to be an obvious routine optimization to one skilled in the art" by asserting that "embossing is not done in practice" (col. 2, line 44), primarily because such optimization is nonobvious to one skilled in the art.

The Examiner rejected claims 27 and 29 as being unpatentable over Kydonieus et al. in view of Steinborn et al. by asserting that Kydonieus' backing layer 34, reservoir layer 35, and diffusion membrane layer 36 alternatively read on the base layer, tie layer, and outer layer of the instant invention, respectively. Furthermore, Kydonieus discloses that the backing layer 34 can be made of aluminum foil, which according to the Examiner is inherently impermeable to drugs. The Examiner again asserted that the use language of the claims is not given patentable weight as failing to contribute to limiting the structure and/or composition of the device. Applicant respectfully points out that the backing of the present invention has a breathable outer layer and a base layer that is not permeable. The amendment to the claims now clearly states the structural and functional relationship of the backing construction to the drug delivery device. The Examiner is asked to explain and provide literature support how an aluminum foil of Kydonieus can anticipate the drug impermeable base layer, and how the diffusion membrane layer can anticipate the embossable, breathable outer layer of the present invention. Again, just flipping the orientation of the Kydonieus device upside down with respect to the orientation to the skin, does not result in the combination of Kydonieus and Steinborn anticipating the present invention. Further, one skilled in the art will not simply flip an element of a multilayered medical device upside down much like an electric engineer will not simply flip a transistor element upside down in an electronic device.

Lastly, the Applicant notes that equating the drug of a drug delivery device with the secondary drug in the tie layer of the present invention is extremely far fetched. Claim 27 specifically states “antagonist to the drug.” According to J. Stenesh, Dictionary of Biochemistry and Molecular Biology, 2nd Ed., 1989, John Wiley & Sons, “antagonist” is defined as “[a] molecule, such as a drug, an enzyme inhibitor, or a hormone, that diminishes or prevents the action of another molecule or receptor site.” Thus, no person skilled in the art will consider a drug to be its own antagonist, since it cannot diminish or prevent its own action. The Examiner is requested to provide literature support that a drug can be its antagonist and that including a drug and its antagonist means including only the drug to one skilled in the art.

Because of the foregoing reasons, the cited references do not render the present invention obvious. Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicant submits the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §102, §103 and §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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